DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

93770d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA CERTIFIED MAIL

WARNING LETTER

FLA-03-14

December 9, 2002

Richard K. Donahue, President
E.M. Adams Co., Inc.
7496 Commercial Circle
Ft. Pierce, Florida 34951

Dear Mr. Donahue:

During an inspection of your establishment located in Ft. Pierce, Florida on August 1-6, 2002, FDA Investigator R. Kevin Vogel determined that your establishment is a manufacturer of patient restraints and sterile surgical trays, which are medical devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection revealed serious violations of the Act.

A. Violations of Quality System Regulation

The devices are adulterated under section 501(h) of the Act, in that your methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The violations include, but are not limited to the following:

1. Your firm failed to adequately validate your sterilization system with a high degree of assurance in accordance with established procedures, violating 21 CFR 820.75. For example:

- Validation deficiencies include failure to conduct worst case determinations of the surgical trays, which would be most difficult for ethylene oxide ("EO") to penetrate; failure to locate documentation of previous validations; failure to enumerate biologic indicators ("BI") to assure a population of 10^6 organisms; failure to include positive control BIs with sterilization loads; failure to complete bioburden studies on components including imported gauze sponges, and failure to document reports of BI growth after sterilization.
- Stability studies have not been conducted to substantiate a two year expiration date.

- Heat distribution studies completed failed to observe the established temperature range.
- Maximum preconditioning transfer time was not followed during validation runs.
- Failure to determine the effect of EO sterilization cycles on lidocaine and Iodophor/Povidone drug products (FDA 483, Item 1A).

2. Your firm failed to adequately validate package seal integrity and aeration processes, violating 21 CFR 820.75(b). For example, your firm failed to document validation of packaging sealers, to report post-sterilization validation of seals, and to document calibration of packaging sealers. Your firm also failed to validate the aeration room and in-chamber aeration operations to assure consistency (FDA 483, Items 1B & 1C).

3. Your firm failed to establish and maintain adequate procedures for the control of storage areas and rooms for product to prevent product damage, deterioration or other adverse effects prior to distribution, violating 21 CFR 820.150. For example, OpSite Dressing used in various surgical trays was stored in an area that was above 90°F. The product is labeled to be stored at or below 25°C or77°F. Many cartons were observed to have an accumulation of dust with some cartons open exposing unwrapped surgical instruments (FDA 483, Item 2).

4. Your firm failed to establish and maintain documented instructions, standard operation procedures, and methods to define and control production to ensure specifications are met, violating 21 CFR 820.70. For example, your firm does not have documented requirement to check for particulates in surgical trays (FDA 483, Item 3).

5. Your firm failed to examine labels for accuracy to assure handling instructions meet requirements prior to release, violating 21 CFR 820.120. For example, your firm failed to place latex warning statement on all trays containing latex bearing components such as latex gloves (FDA 483, Item 5).

6. Your firm failed to establish and maintain procedures for implementing corrective and preventive actions, violating 21 CFR 820.100 (FDA 483, Item 6).

7. Your firm failed to establish and maintain procedures to control the design process of the devices that are subject to the requirements of 21 CFR 820.30 (FDA 483, Item 7).

B. Violations of Medical Device Reporting Regulation

The inspection also revealed that your devices are misbranded within the meaning of section 502(t)(2) of the Act, in that your firm failed to furnish material or information required by or under section 519 respecting the devices. The violations include, but are not limited to the following:

1. Your firm failed to submit adverse event medical device reports ("MDR") within 30 days of becoming aware of information that reasonably suggests that your device may have caused or contributed to a death or serious injury, violating by 21 CFR 803.50(a). For example, your firm received a User Facility Med Watch report dated November 2, 2000 involving an Adamco patient restraint. In this adverse event, the patient was found with no pulse but revived, and it was later determined that the patient restraint had been used incorrectly. This is a reportable event under 21 CFR 803.50, but your firm failed to report this event to the FDA (FDA 483, Item #4B).

2. Your firm failed to establish and maintain written MDR procedures, violating 21 CFR 803.17.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. During the inspection you promised to correct the objectionable conditions listed on the FDA 483 (Inspectional Observations), however, we have not received any response from you addressing the deficiencies noted above.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including (1) the

time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Emma R. Singleton
Director, Florida District